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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,869	12/08/2000	Georgia L. Helmer	5051-473	3142
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MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
			EXAMINER MARVICH, MARIA	
			ART UNIT 1633	PAPER NUMBER

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/733,869

Applicant(s)

HELMER ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

This office action is in response to an amendment filed 4/25/05 and 8/15/05. Claims 2-3 have been cancelled. Claims 1 and 13 have been amended. Claims 1 and 4-18 are pending in the application.

#### ***Drawings***

Figure 8 is objected to under 37 CFR 1.83(a) because it fails to show any details as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). The image is a photograph of a Southern blot and arrows indicate bands. However, no bands are visible. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### ***Response to Argument***

Receipt of proposed drawing changes in the amendment filed 4/25/05 is acknowledged.

#### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 5, 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite in that the metes and bounds of “said nucleotide of interest” is unclear. The nucleotide of interest is said to be flanked by a single recombination site positioned 5' thereto. As claim 5 depends from claim 1, which recites that the nucleotide of interest is flanked by a pair of identical recombination sites, one on each side, it is unclear how the sequence can also be flanked by a single recombination site. Is the recombination site recited in claim 5 in addition to that of base claim 1 or is one of the original recombination sites deleted to generate the nucleotide sequence of interest in claim 5 or is there a single recombination site 5' to the nucleotide of interest as opposed to two sites flanking the nucleotide? It would be remedial to clarify the language of the claim to indicate which of these is the case. **This is a new rejection necessitated by applicants' amendment.**

Claim 6 is vague and indefinite in that the metes and bounds of “said nucleotide of interest” is unclear. Base claim 1 already recites that the nucleotide of interest is flanked by a pair of identical recombination sites one on each side, which would place them 5' and 3' of the nucleotide sequence. Therefore, it is unclear if the recombination sites recited in claim 6 are the same as or in addition to those of base claim 1?

If they are the same, claim 6 does not further limit claim 1. If they were different, it would be remedial to indicate that. **This is a new rejection necessitated by applicants' amendment.**

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Claim 13 is vague and indefinite in that the metes and bounds of “transforming step is carried out *in vitro* on a population of cells, a first sub-population of which” are unclear. As recited, it appears that the first subpopulation of cells has been transformed and is being retransformed by the method of step (b). However, the claim could also be interpreted as meaning that meaning that with in the population of cells, some are transformed and some are not. It would be remedial to clarify which of these is the case. **This is a new rejection necessitated by applicants’ amendment.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Baszczynski et al (2004/0005713; see entire document). **This is a new rejection necessitated by applicants’ amendment.**

Baszczynski et al teach a method for the targeted insertion of a nucleotide of interest into a specific chromosomal site within a plant cell using a plant cell with a target site flanked by a site recognized by a site-specific recombinase (paragraph 0027). The plant cell is transformed with an Agrobacterium T-DNA carrying a nucleotide sequence of interest flanked by a pair of identical recombination sites that correspond to the recombination site on the target site (see e.g.

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paragraph 0010). Given that the accepted meaning of correspond is “similar, equivalent or consistent”, the target site corresponds to that on the T-DNA vector. For example, the T-DNA comprises the identical recombination sites, FRT1, flanking the nucleotide of interest. The recombination site at the target site is FRT5, which is similar to FRT1 (see e.g. figure 3).

Baszczyński et al teach that the method does not require insertion into the chromosome.

However, as evidenced by Wei et al, T-DNA inherently integrates into plant cells following *Agrobacterium* transformation (see e.g. page 1537, paragraph 3). This publication by Wei et al states that the mechanism of transformation has progressed in recent years to provide details previously unknown whereas Baszczyński et al readily admit that the mechanism is unknown (see e.g. paragraph 0005). Hence, Wei et al provide elucidation of the steps following *Agrobacterium* transformation that were not known by inherent in Baszczyński et al (see e.g. abstract).

Baszczyński et al teach that the T-DNA forms an excision circle (see e.g. figure 2 and paragraph 0018) that then recombines with the recombination site at the target site on the chromosome (see e.g. figure 3) as recited in claims 1 and 6. The target site can be flanked on either site by a pair of recombination sites (see e.g. paragraph 0027) as recited in claim 4. If claim 5 can be interpreted as meaning that there is a single recombination site 5' to the nucleotide of interest as opposed to two sites on the 5' site of then as demonstrated in figure 2, the DNA of interest is so positioned with loxP'. DNA is stably introduced into the cell via *Agrobacterium* mediated transformation (see e.g. paragraph 0064-0065) as recited in claim 7. The recombinase is an integrase such as FLP and the recombination sites are FRT as recited in claims 8-10 (see e.g. paragraph 0042 and 0038). The plant is a dicot (see e.g. paragraph 0072), which includes

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many plants with genomes greater than 500 megabases as recited in claims 11 and 12. The method involves Agrobacterium mediate transformation methods which involves transformation of meristem followed by selection (see e.g. paragraph 0074-0075) with antibiotics such as kanamycin (see e.g. paragraph 0083) to select those cells that have been transformed as there are usually two populations of cells inherently produced by Agrobacterium transformation, those transformed and those that are not as recited in claims 13 and 14. The cells are also transformed with recombinase resulting in plant cells, plants, seed and pollen (see e.g. paragraph 0068 and 0072) as recited in claims 15-18.

### ***Conclusion***

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

October 26, 2005



**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**